DEC 2 6 2001 K012731

510(k) SUMMARY

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
SOLOCare Plus Multipurpose Solution

1. **Submitter Information**
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person:Steven Dowdley
Telephone No. 678-415-3897

2. **Device Name**
Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: SOLOCare Plus Multipurpose Solution

3. **Predicate Devices**
SOLOCare Multipurpose Solution
COMPLETE ComfortPlus Multipurpose Solution

4. **Description of the Devices**
SOLO-Care Plus Multi-Purpose Solution is a sterile aqueous solution containing sodium chloride, bis-tris propane, pluronic F127, cremephor and preserved with edetate disodium dihydrate 0.025% and polyhexanide 0.0001%.

5. **Indications for Use**
SOLO-Care™ Plus Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, protein removal, and storing soft (hydrophilic), rigid gas permeable (fluoro silicon acrylate and silicon acrylate) contact lenses as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**
A series of preclinical and clinical studies were completed to demonstrate the substantial equivalence of SOLO-Care™ Plus Multi-Purpose Solution to the predicate device(s). All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the solution is non-toxic and biocompatible, and is comparable to other currently marketed soft contact lens solutions. Results from all tests demonstrate the substantial equivalence to previously FDA approved predicate device.

Lens Compatibility Data:
There was no significant difference between SOLO-Care™ Plus Multi-Purpose Solution and the control solution, with respect to optical and physical changes in the measured properties of the lenses.

In Vitro Cleaning Efficacy
This study was conducted to compare the protein cleaning efficacy of SOLO-Care™ Plus Multi-Purpose Solution to currently marketed SOLO-Care Multipurpose Solution. Results of the study showed that SOLOCare Plus is substantially equivalent to SOLO-Care Multipurpose Solution in terms of daily protein removal.

Cytotoxicity
A series of cytotoxicity studies were conducted to demonstrate the safety of SOLO-Care Multipurpose Solution. Results of the testing demonstrated that SOLO-Care Multipurpose Solution is non-cytotoxic and is a non-irritant.

Microbiological
A two series of microbiological studies were conducted to demonstrate the microbial efficacy SOLO-Care Multipurpose Solution. The first series evaluated the product under a rub/rinse regimen, while the second regimen evaluated the performance of the product under a pre-rinse/ no rub regimen. In the studies, both regimen demonstrated that SOLO-Care Multipurpose Solution met the stand-alone criteria with organic load for disinfection. Additionally, the regimen test criteria was also meet for both regimen for SOLOCare Plus.

Clinical Testing
A series of clinical studies have been conducted to support the substantial equivalency of SOLO-Care Plus to currently marketed SOLO-Care Multipurpose Solution. As previously discussed, the proposed solution will be marketed with two sets of instructions for use, therefore multiple clinical studies will be discussed in this section. Below are the clinical summaries of the relevant studies conducted using SOLO-Care Plus.

Study #1 "BTP-crème Internal Clinical Evaluation
The primary objective of this clinical study was to demonstrate that SOLO-Care plus would be acceptable to proceed to a validation clinical study. The study was a two-week, prospective, randomized, investigator masked, contralateral study. A total of fifteen subjects were enrolled in this study. The predicate or control device selected for this study was currently marketed SOLO-Care Multipurpose Solution. The regimen used for the test product was a rub/rinse cleaning step, followed by a minimum 5 minute soak in SOLO-Care Plus. The regimen used for the control product was a rub/rinse cleaning step, followed by a minimum 10 minute soak in SOLO-Care Multipurpose Solution.

In this study, SOLO-Care Plus was found to be an effective multipurpose solution for soft contact lenses. Findings for safety variables were low with little difference between the test solution and the control. Comfort levels were high at all times, and the subjective complaints were low in number and acceptable. Based on the data collected in this study SOLO-Care Plus is substantially equivalent to SOLO-Care Multipurpose Solution.

Study #2 "BTP-crème Internal Clinical Evaluation
The primary objective of this clinical study was to demonstrate that SOLO-Care Plus was substantially equivalent to SOLO-Care Multipurpose Solution. This study was a five investigator, three-month, prospective, investigator masked, contralateral study. A total of ninety-five subjects were enrolled in this study. The predicate or control device selected for this study was currently marketed SOLO-Care Multipurpose Solution. The regimen used for the test product was a rub/rinse cleaning step, followed by a minimum 5 minute soak in SOLO-Care Plus. The regimen used for the control product was a rub/rinse cleaning step, followed by a minimum 10 minute soak in SOLO-Care Multipurpose Solution.

In this study SOLO-Care Plus was found safe and effective multipurpose solution for soft contact lenses and was found to be substantially equivalent to SOLOCare Multipurpose Solution.

Study #3 "BTP Crème versus Complete U.K. Clinical Trial
The primary objective of this clinical study was to demonstrate non-inferiority between BTP Crème (SOLO-Care Plus) using a no rub regimen as compared Complete (no rub with a pre and post rinse) Multipurpose Solution. The study was a one-month prospective, randomized, investigator masked, contralateral study. The visit schedule consisted of an initial/ dispensing, a two-week

follow-up, and a one-month final visit. A total of seventy-three subjects were enrolled in this study. The predicate or control device selected for this study was Allergan Complete Comfortplus Multipurpose Solution. The regimen used for the test product was a no rub and no rinse regimen followed by a 6-hour soak in SOLO-Care Plus 5-minute soak in SOLO-Care Plus. The regimen used for the control product was a pre-rinse, no rub, followed by a 6-hour soak and a post rinse in Complete Comfortplus Multipurpose Solution.

The data in this clinical trial was consistent in showing substantial equivalence between SOLOCare Plus without a rub and rinse versus Complete Comfortplus Multipurpose Solution with a pre and post rinse with overnight soaking.

7. **Substantial Equivalence**

The date provided in this 510(k) submission concludes that SOLO-Care Plus Multipurpose Solution is substantially equivalent to SOLO-Care Multipurpose Solution and Complete Comfortplus Multipurpose Solution for cleaning, rinsing, chemical (not heat) disinfecting, protein removal, and storing soft (hydrophilic) contact lenses as recommended by your eye care practitioner. In addition, SOLO-Care Plus Multipurpose Solution was substantially equivalent to SOLO-Care Multipurpose Solution with an indication for use with rigid gas permeable (fluoro silicon acrylate and silicon acrylate) lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 6 2001

CIBA Vision Corporation
c/o Steven Dowdley, RAC
11460 Johns Creek Pkwy.
Duluth, GA 30097

Re: K012731
Trade/Device Name: SOLO-Care Plus Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft Lens Products
Regulatory Class: Class II
Product Code: LPN
Dated: August 13, 2001
Received: August 15, 2001

Dear Mr. Dowdley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: *This is a new 510 (k) Notification. (Number to be assigned)*
K012731

Device Name: SOLO-Care Plus Multipurpose Solution

Indications for Use:
SOLO-Care™ Plus Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, protein removal, and storing soft (hydrophilic), rigid gas permeable (fluoro silicon acrylate and silicon acrylate) contact lenses as recommended by your eye care practitioner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☒

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number 012731